



# Changes in Quality Assurance Policies for the Removal Program

Office of Emergency and Remedial Response  
Immediate Office

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The Office of Emergency and Remedial Response (OERR) is revising the 1990 *Quality Assurance/Quality Control Guidance for Removal Activities* to address changes in Agency-wide quality assurance policies. Removal program quality assurance (QA) elements are contained in the National Contingency Plan (NCP, 40 CFR Part 300) as well as Agency-wide documents. For each non-time-critical and time-critical response activity, the Removal program personnel should perform systematic, project-specific planning and document the results in the form of QA Sampling Plans. These plans should be approved prior to any data collection. Regional project-specific QA Sampling Plans can refer to standard language in a programmatic Regional Removal Program Order. QA Sampling Plans for emergency responses are encouraged, but do not require approval prior to implementation. Following an emergency response, a report of the sampling protocols and quality assurance specifications implemented should be provided.

## INTRODUCTION

In April 1990, the Office of Emergency and Remedial Response (OERR) prepared the Office of Solid Waste and Emergency Response (OSWER) Directive 9360.1-01, *Quality Assurance/Quality Control Guidance for Removal Activities* (the Removal QA Guidance), which was based on the existing Agency-wide quality assurance (QA) policies.

Since then, the existing Agency-wide quality assurance documents were revised as follows:

- EPA Order 5360.1 A2, *Quality Assurance and Program Requirements for the Mandatory Agency-Wide Quality System* (the revised Quality Order); and
- EPA 5360 A1, the *EPA Quality Manual for Environmental Programs* (the Quality Manual).

OERR recognized the need to update the Removal QA Guidance in light of these Agency-wide policy changes. As part of the process of revising the Removal QA Guidance, OERR is issuing a series of QA Technical Information Bulletins focusing on some of the more

significant QA changes now impacting the Removal program.\*

## ORIGINS OF QUALITY POLICY

QA policies for the Removal program come from a variety of sources, including Agency-wide policies and the National Contingency Plan (NCP). Ideally, information from these disparate sources is synthesized by OERR, and issued to the Regional offices implementing the Removal program activities.

This bulletin was written in part to provide detailed practical guidance to the Removal program in implementing the various and sometimes seemingly inconsistent QA policies.

As stated in the revised Quality Order, it is Agency policy that all environmental programs performed by or directly for EPA through EPA-funded extramural agreements be supported by individual quality systems.

In July 1998, EPA issued a revised Quality Order (EPA Order 5360.1 CHG 1), which re-affirmed the policy defined by EPA Order 5360.1 (April 1984), and

\* The discussion in this document is intended solely as guidance. This document is not a regulation. It does not impose binding legal requirements. EPA retains the right to adopt approaches on a case-by-case basis that differ from those described in this guidance, where appropriate. This guidance document interprets Agency policies on quality assurance. This guidance document may be revised without notice.

expanded that policy to accommodate the current and evolving needs of the Agency. Subsequently, EPA has issued EPA Order 5360.1 A2 (May 5, 2000), which addressed administrative reporting changes within the Agency, but made no additional substantive changes to the Quality Order revised in 1998.

The revised Quality Order defines the minimum quality systems supporting EPA environmental programs that encompass the following:

- The collection, evaluation, and use of environmental data by or for EPA; and
- The design, construction, and operation of environmental technology by EPA.

This revised Quality Order also applies to any collection and use of environmental data pertaining to the occupational health and safety of personnel in the field (e.g., chemical dosimetry, radiation dosimetry).

According to the revised Quality Order, “[a] consistent, Agency-wide Quality System will provide, when implemented, the needed management and technical practices to assure that environmental data used to support Agency decisions are of adequate quality and usability for their intended purpose.” *Data quality and usability are directly related to planning and performing a sufficient level of QA and quality control (QC) activities.*

## PROGRAM-LEVEL QUALITY PLANNING

As part of its mission to provide a quality system, National Program Office (NPO) OERR establish their own Quality Management Plans (QMPs). This plan, an evolution of the QA Program, should be prepared and updated every five years. It should specify the organization's structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and interfaces for those planning, implementing, documenting, and assessing all activities performed by or overseen by the organization.

The QMP is established at the EPA Headquarters level. For removal programs, the initial responsibility for the QMP is with OERR. In addition to OERR's QMP, each Region should develop a QMP. These plans are tailored to the specific operational needs of the Regional office. The OERR QMP issues Removal program activity QA parameters to the Regions; the Regional QMPs then address them.

## NEW POLICIES FOR PROJECT-SPECIFIC PLANNING

The revised Quality Order sets forth, among other

things, that a logical, systematic planning approach be used to design an effective data collection and evaluation program. One such process is the Agency's Data Quality Objectives (DQO) Process. The results of systematic planning, including the data use objectives and the collection strategies decided upon, should be documented in a QA project plan. A separate QA Technical Information Bulletin, “Systematic Planning Processes for the Removal Program,” describes the purposes and components of systematic planning in more detail.

## PROJECT-SPECIFIC PLANNING

This revised Quality Order requires for QA Project Plans (QAPPs), or equivalents, as defined in the preceding QMP, to be developed for all significant projects and tasks involving environmental data. Additionally, the QAPPs or QAPP-equivalents should be reviewed and approved by the EPA QA Manager (or an authorized representative defined in the QMP). QAPPs or QAPP-equivalents should be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect health and the environment or operations under police powers.

### Importance of the QAPP

According to the Agency Quality Manual (also updated in May 2000), the QAPP is a critical planning document for any environmental data operation. The QAPP documents how environmental data operations are planned, implemented, documented, and assessed during the life cycle of a program, project, or task. The ultimate success of an environmental program or project depends on the adequacy and sufficiency of the quality of the environmental data collected and used in decision-making. This may depend significantly on the adequacy of the QAPP and its effective implementation.

### Removal Program Support for QAPPs

The NCP states the following in 40 CFR 300.415(b)(4)(ii):

*If environmental samples are to be collected, the lead agency shall develop sampling and analysis plans that shall provide a process for obtaining data of sufficient quality and quantity to satisfy data needs. Sampling and analysis plans shall be reviewed and approved by EPA. The sampling and analysis plans shall consist of two parts:*

- (A) The field sampling plan, which describes the number, type, and location of samples and the type of analyses; and*
- (B) The quality assurance project plan,*

*which describes policy, organization, and functional activities and the data quality objectives and measures necessary to achieve adequate data for use in planning and documenting the removal action.*

This language was included in an NCP revision on March 8, 1990. The Preamble to this regulation published in the *Federal Register* (55 FR 8694) included more explanatory language for 40 CFR 300.415, *Removal Action*, as follows:

*... EPA believes that, when samples will be taken, it is appropriate to describe sampling requirements for non-time-critical removal actions to ensure that data of sufficient quality and quantity will be collected for this type of action.*

*EPA also notes that portions of the QAPP may incorporate by reference non-site-specific standardized portions of already-approved QAPPs, especially those portions addressing policy and organization, or describing general functional activities to be conducted at a site to ensure adequate data. This eliminates the necessity to reproduce non-site-specific quality assurance procedures for every site. [emphasis added]*

### ***The Elements of the QAPP***

To meet the requirements for a QA Program for the Removal program, the Project Plan is divided into two functional elements: a generic Branch QA Project Plan," and a response-specific Sampling Plan. When combined, these documents comprise the 24 elements described in the Quality Manual, Chapter 5 (Table 1), as well as the requirements of the NCP, 40 CFR 300.415.

### ***Responsibilities for Branch-Level QAPPs***

The Branch QA Project Plan should be prepared by the Regional Removal Branch and addresses only the elements generic to all Removal activities conducted in the Region. These might include calibration procedures for each instrument, decontamination procedures for each analyte class, and the generic corrective action process. The Branch Plan should be reviewed annually and updated periodically to reflect any operational changes in the Region.

### ***Elements of the Response-specific QAPP***

The response-specific QA Sampling Plan should be prepared for each site where sampling will be

**Table 1: General QAPP Content**

#### **Group A, Project Management**

A1 Title and Approval Sheet  
A2 Table of Contents  
A3 Distribution List  
A4 Project/Task Organization  
A5 Problem Definition/Background  
A6 Project/Task Description  
A7 Quality Objectives and Criteria for Measurement Data  
A8 Special Training/Qualification  
A9 Documentation Standards

#### **Group B, Measurement Acquisition**

B1 Sampling Process Design (General Design)  
B2 Sampling Methods  
B3 Handling and Custody  
B4 Instrument Methods  
B5 Quality Assurance  
B6 Instrument Prevent Testing, Inspection, and Maintenance  
B7 Instrument Calibration and Frequency  
B8 Inspection/Acceptance for Supplies and Materials  
B9 Instrumentation (Non-direct Measurements)  
B10 Data Management

#### **Group C, Assessment/Oversight**

C1 Assessments and Response Actions  
C2 Reports to Management

#### **Group D, Data Validation and Usability**

D1 Data Review, Validation, and Verification  
D2 Validation and Verification Methods  
D3 Reconciliation with User Needs

Source: Adapted from Chapter 5, Quality Manual, May 2000

performed. The plan also addresses those elements specific to the site, such as sample collection and analysis. The response-specific QA Sampling Plan should be prepared for each response and amended when the scope of work changes significantly from the scope of work described in any previous plan. Elements that are not addressed in the Branch Plan should be included in the QA Sampling Plan.

Certain elements should be addressed in the response-specific plan. For example, to meet element A7, Quality Objectives and Criteria for Measurement Data, the data use objectives during the specific effort should be known and documented. Proper use of a systematic planning process results in the identification of the

“data categories” appropriate to the specific response. Refer to the QA Technical Information Bulletin, “Applicability of Superfund Data Categories to the Removal Program,” for additional discussion of data categories selection and use.

#### ***When Should the QAPP be Prepared?***

The revised Agency-wide Quality Order states: “QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.” Applying this to the Removal program, only emergency responses would be included in this exemption. Although the NCP specifically calls for sampling and analysis plans (e.g., QA Sampling Plans) for *non-time-critical* responses (responses with at least 6 months lead time), the revised Quality Order does not exempt *time-critical* responses (responses with less than 6 months lead time). Thus, *time-critical* responses should also have a QA Sampling Plan prepared.

OERR policy for *emergency* responses, where the release *requires* that response activities begin on-site *within hours* of the Agency’s determination that removal action is appropriate, is that a QA Sampling Report (or equivalent) be submitted no later than 30 days after the response date for documentation purposes. It is recommended that this QA Sampling Report describe the sampling event that occurred by containing the types of information that would have been included in a QA Sampling Plan.

In practice, operations are based on Sampling Plan templates, finalized and if needed, real-time emergency response sampling and QA.

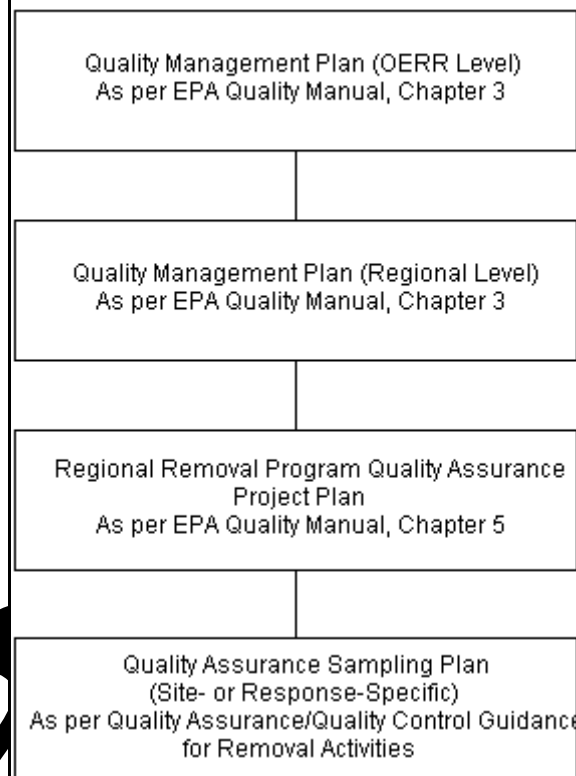
In all other cases, however, the QA Sampling Plan should be written and approved prior to initiating the response activities.

#### **SUMMARY OF HIERARCHY OF QA DOCUMENTATION**

Quality assurance planning, implementation, and documentation for the Removal program are documented at several levels (Figure 1). Source documents at each level are listed.

**NOTE:** the 1990 *Quality Assurance/Quality Control Guidance for Removal Activities* is under revision.

**Figure 1: EPA Quality Assurance Documentation**



#### **REFERENCES**

1. U.S. Environmental Protection Agency, *National Oil and Hazardous Substances Contingency Plan*, 40 CFR Part 300, as amended.
2. U.S. Environmental Protection Agency, *EPA Quality Manual For Environmental Programs*, EPA Manual 5360 A1, Office of Environmental Information, May 2000.
3. U.S. Environmental Protection Agency, *Policy And Program Requirements For The Mandatory Agency-wide Quality System*, EPA Order 5360.1 A2, May 5, 2000.
4. U.S. Environmental Protection Agency, *Systematic Planning Processes for the Removal Program*, Quality Assurance Technical Information Bulletin, February 2003. (TBD).
5. U.S. Environmental Protection Agency, *Applicability of Superfund Data Categories to the Removal Program*, Quality Assurance Technical Information Bulletin, February 2003. (TBD).